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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,273	08/27/2001	Gust H. Bardy	032580.0027.UTL	5279

22440 7590 09/24/2003

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[REDACTED] EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
3762	7

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/940,273	BARDY ET AL.
	Examiner	Art Unit
	Kristen L Drosch	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 April 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-219 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-219 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-136, drawn to implantable cardioverter defibrillators, classified in class 607, subclass 4.
  - II. Claims 137-219, drawn to methods of implanting implantable cardioverter defibrillators, classified in class 607, subclass 4.
2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in a materially different process of using that product such as a method of implanting the ICD in the sub-clavicle area and implanting the second electrode into the heart via the venous system, or the method of implanting an ICD into the abdominal area, and implanting two patch electrodes on the heart in two different locations.
3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

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4. This application contains claims directed to the following patentably distinct species of the claimed invention of Group I:

Species I – implantable cardioverter-defibrillator of Figures 1-3

Species II – implantable cardioverter-defibrillator of Figures 12-13

Species III – implantable cardioverter-defibrillator of Figures 14-15

Species IV - implantable cardioverter-defibrillator of Figures 19-21

Species VI - implantable cardioverter-defibrillator of Figure 23A-23B

Species VII - implantable cardioverter-defibrillator of Figure 24A –24C

Species VIII - implantable cardioverter-defibrillator of Figure 25A-25B,

Species IX - implantable cardioverter-defibrillator of Figures 26A-26C

Species X - implantable cardioverter-defibrillator of Figure 28.

5. If applicant elects the invention of Group I, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Restriction between the ICD species comprising a ceramic housing, the ICD species comprising a titanium alloy housing, the ICD species comprising a stainless steel housing, and the ICD species comprising a polymeric housing are considered clearly unpatentable over each other, therefore restriction between those species is not required.

Restriction between the species shown in Fig. 23A, and the species in Fig. 23B are considered clearly unpatentable over each other, therefore restriction between those species is not required.

Restriction between the species shown in Fig. 24B, and the species in Fig. 24C are considered clearly unpatentable over each other, therefore restriction between those species is not required.

Restriction between the species shown in Fig. 25A, and the species in Fig. 25B are considered clearly unpatentable over each other, therefore restriction between those species is not required.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the *allowance* of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Drolesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

*Kristen Drolesch*

kld

*Kennedy Schatz*  
KENNEDY SCHAEETZLE  
PRIMARY EXAMINER  
9-17-03